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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bacitracin Methylene Disalicylate and Fenbendazole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved bacitracin methylene disalicylate and fenbendazole Type A medicated articles to make combination Type B and C medicated feeds for growing and finishing swine and pregnant sows for the removal of various internal parasites, for increased rate of weight gain and improved feed efficiency, for control of swine dysentery associated with *Treponema hyodysenteriae*, and for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens*. Technical corrections are also being made.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-144 that provides for use of BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate) and SafeGuard® (18.1, 36.2, or 90.7

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g/lb fenbendazole) Type A medicated articles to make combination Type B and C medicated feeds for growing and finishing swine and pregnant sows.

For growing and finishing swine, the Type A medicated articles are used to make combination Type B medicated feeds that contain 300 to 1,780 grams per ton (g/ton) of bacitracin methylene disalicylate and 300 to 17,740 g/ton of fenbendazole and combination Type C medicated feeds that contain 10 to 30 g/ton of bacitracin methylene disalicylate and 10 to 300 g/ton of fenbendazole. The combination Type C medicated feeds are used for increased rate of weight gain and improved feed efficiency; and for the removal of adult-stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, and intestinal forms) large roundworms (*Ascaris suum*); adult-stage nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worms (*Hyoststrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); and adult and larvae kidneyworms (*Stephanurus dentatus*).

For growing and finishing swine and for pregnant sows, the Type A medicated articles are used to make Type B medicated feeds that contain 7,460 to 14,837 g/ton of bacitracin methylene disalicylate and 300 to 17,740 g/ton of fenbendazole and Type C medicated feeds that contain 250 g/ton of bacitracin methylene disalicylate and 10 to 300 g/ton of fenbendazole.

The combination Type C medicated growing and finishing swine feeds are used for the control of swine dysentery associated with *T. hyodysenteriae* in growing and finishing swine on premises with a history of swine dysentery but where signs of disease have not yet occurred, or following an approved treatment of the disease; and for the removal of adult-stage lungworms (*M. apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, and intestinal forms) large roundworms (*A. suum*); adult-stage nodular worms (*O. dentatum*, *O. quadrispinulatum*); small stomach worms (*H. rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*T. suis*); and adult and larvae kidneyworms (*S. dentatus*).

The combination Type C medicated sow feeds are used for the control of clostridial enteritis in suckling pigs caused by *C. perfringens*; and for the removal of adult stage lungworms (*M.*

apri and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, and intestinal forms) large roundworms (*A. suum*); adult-stage nodular worms (*O. dentatum*, *O. quadrispinulatum*); small stomach worms (*H. rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*T. suis*); and adult and larvae kidneyworms (*S. dentatus*).

The NADA is approved as of April 7, 2000, and 21 CFR 558.76 and § 558.258 (21 CFR 558.258) are amended to add new entries to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, § 558.258 is amended to redesignate paragraph (c) as paragraph (d) and add paragraph (c) to reflect a newer format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.76 is amended by adding paragraph (d)(3)(xxii) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xxii) Fenbendazole as in § 558.258.

3. Section 558.258 is amended by redesignating paragraph (c) as paragraph (d) and reserving paragraph (c), and by adding paragraphs (d)(1)(vi) and (d)(1)(vii) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(c) [Reserved]

(d) * * *

(1) * * *

(vi) *Amount.* Fenbendazole, 10 to 300 grams per ton (to provide 9 milligrams per kilogram body weight), and bacitracin methylene disalicylate, 10 to 30 grams per ton.

(A) *Indications for use.* As an anthelmintic (as provided in paragraph (d)(1)(i)(A) of this section) and for increased rate of weight gain and improved feed efficiency in growing/finishing swine.

(B) *Limitations.* Feed as sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

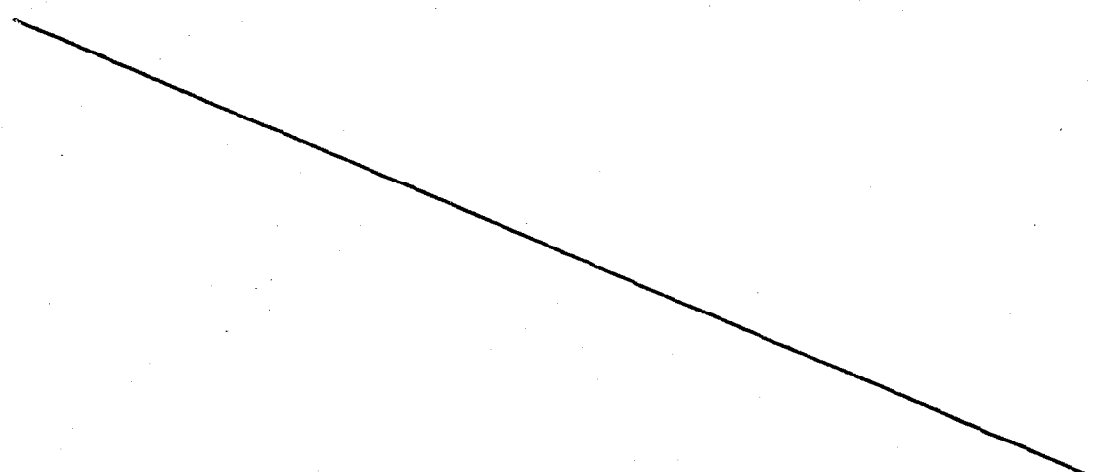
(vii) *Amount*. Fenbendazole, 10 to 300 grams per ton, and bacitracin methylene disalicylate, 250 grams per ton.

(A) *Indications for use*—(1) *Growing/finishing swine*. As an anthelmintic (as provided in paragraph (d)(1)(i)(A) of this section) and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.

(2) *Pregnant sows*. As an anthelmintic (as provided in paragraph (d)(1)(i)(A) of this section) and for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens*.

(B) *Limitations*—(1) *Growing/finishing swine*. Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 pounds. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(2) *Pregnant sows*. Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to



parasites, retreatment may be needed after 4 to 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

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Dated: 6/19/00
June 19, 2000

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Jan Windsor

S F Sundlof
Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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